

## PCT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C. 20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 15 September 2000 (15.09.00)	
International application No. PCT/EP00/00137	Applicant's or agent's file reference FB/BM45351
International filing date (day/month/year) 10 January 2000 (10.01.00)	Priority date (day/month/year) 15 January 1999 (15.01.99)
Applicant RUELLE, Jean-Louis	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
01 August 2000 (01.08.00)

☐ in a notice effecting later election filed with the International Bureau on:  
\_\_\_\_\_

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Charlotte ENGER  Telephone No.: (41-22) 338.83.38
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# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>FB/BM45351</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/EP 00/00137</b>	International filing date (day/month/year) <b>10/01/2000</b>	(Earliest) Priority Date (day/month/year) <b>15/01/1999</b>
Applicant <b>SMITHKLINE BEECHAM BIOLOGICALS S.A. et al</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☒ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

### 4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

**NEISSERIA MENINGITIDIS ANTIGEN**

### 5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

### 6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No.

EP 00/00137

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/31 C07K14/22 C07K16/12 A61K39/095 A61K39/40

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12N C07K A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 99 57280 A (PIZZA MARIAGRATIA ;MORA MARIROSA (IT); RAPPUOLI RINO (IT); GALEOTT) 11 November 1999 (1999-11-11) page 3, paragraph 4 SEQ ID NO. 2606 claims 12-15	1-24
A	--- WO 98 02547 A (INST NAT SANTE RECH MED ;MAX PLANCK GESELLSCHAFT (DE); SMITHKLINE) 22 January 1998 (1998-01-22) page 1, line 5 - line 10 claims 23,28-32	1-24
A	--- WO 96 29412 A (IAF BIO VAC INC ;BRODEUR BERNARD R (CA); MARTIN DENIS (CA); HAMEL) 26 September 1996 (1996-09-26) page 1, line 5 - line 21 --- -/--	1-24

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

11 April 2000

Date of mailing of the international search report

20.04.00

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Mata Vicente, T.

## INTERNATIONAL SEARCH REPORT

International Application No

EP 00/00137

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 93 07172 A (PASTEUR MERIEUX SERUMS VACC) 15 April 1993 (1993-04-15) page 3, line 3 - line 26 ---	1-24
A	WO 96 12020 A (UNIV OREGON HEALTH SCIENCES ;STOJILJKOVIC IGOR (US); SO MAGDALENE) 25 April 1996 (1996-04-25) abstract ---	1-24
A	WO 96 31618 A (UNIV NORTH CAROLINA) 10 October 1996 (1996-10-10) claims 25-28,30,31,41-44 ---	1-24
A	WO 92 01460 A (UNIV NORTH CAROLINA) 6 February 1992 (1992-02-06) page 6, line 7 - line 13 page 7, line 18 - line 21 ---	1-24
A	WO 90 06696 A (RIJKINSINSTITUUT VOOR VOLKSGEZ ;PRAXIS BIOLOG INC (US)) 28 June 1990 (1990-06-28) page 3, paragraph 3 claim 1 -----	1-24

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

EP 00/00137

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9957280	A	11-11-1999	NONE	
WO 9802547	A	22-01-1998	FR 2751000 A AU 3697797 A EP 0951552 A	16-01-1998 09-02-1998 27-10-1999
WO 9629412	A	26-09-1996	AU 716225 B AU 4934396 A BR 9607651 A CA 2215161 A CZ 9702914 A EP 0815234 A HU 9702387 A JP 11500624 T NO 974264 A PL 322363 A SI 9620035 A SK 125597 A	24-02-2000 08-10-1996 17-11-1998 26-09-1996 14-01-1998 07-01-1998 28-05-1998 19-01-1999 13-11-1997 19-01-1998 31-12-1998 03-06-1998
WO 9307172	A	15-04-1993	FR 2682114 A AT 174930 T AU 668522 B AU 2764092 A CA 2096411 A DE 69227984 D DE 69227984 T EP 0560969 A ES 2128358 T FI 932490 A GR 3029580 T HU 69929 A JP 6503364 T NO 932009 A US 5618540 A US 5928650 A	09-04-1993 15-01-1999 09-05-1996 03-05-1993 04-04-1993 04-02-1999 12-05-1999 22-09-1993 16-05-1999 01-06-1993 30-06-1999 28-09-1995 14-04-1994 20-07-1993 08-04-1997 27-07-1999
WO 9612020	A	25-04-1996	US 5698438 A AU 705509 B AU 4007395 A CA 2203116 A EP 0793720 A FI 971634 A HU 77048 A JP 10508469 T NO 971768 A	16-12-1997 27-05-1999 06-05-1996 25-04-1996 10-09-1997 16-06-1997 02-03-1998 25-08-1998 03-06-1997
WO 9631618	A	10-10-1996	AU 5537096 A CA 2217522 A EP 0830456 A JP 11503322 T	23-10-1996 10-10-1996 25-03-1998 26-03-1999
WO 9201460	A	06-02-1992	AU 8298991 A CA 2087160 A EP 0539492 A JP 6502394 T	18-02-1992 17-01-1992 05-05-1993 17-03-1994
WO 9006696	A	28-06-1990	NL 8803111 A NL 8900030 A	16-07-1990 01-08-1990

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

EP 00/00137

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9006696 A		NL 8901612 A	16-07-1990
		AT 120093 T	15-04-1995
		AU 640118 B	19-08-1993
		AU 4821990 A	10-07-1990
		DE 68921895 D	27-04-1995
		DE 68921895 T	07-09-1995
		DK 117491 A	15-08-1991
		EP 0449958 A	09-10-1991
		ES 2070312 T	01-06-1995
		JP 6503465 T	21-04-1994
		NL 8900036 A	16-07-1990
		NO 305463 B	07-06-1999
		CA 2000735 A	06-07-1990
		CA 2007248 A	06-07-1990
		DE 8901378 U	23-03-1989
		DK 511389 A	07-07-1990
		EP 0377233 A	11-07-1990
		US 5057007 A	15-10-1991
		PT 92807 A,B	31-07-1990
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# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

PRIVETT, Kathryn L.  
SMITHKLINE BEECHAM  
Two New Horizons Court  
Brentford  
Middlesex TW8 9EP  
GRANDE BRETAGNE

27 APR 2001

**PCT**

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT  
(PCT Rule 71.1)

Date of mailing  
(day/month/year) 25.04.2001

Applicant's or agent's file reference  
FB/BM45351

## IMPORTANT NOTIFICATION

International application No.  
PCT/EP00/00137

International filing date (day/month/year)  
10/01/2000

Priority date (day/month/year)  
15/01/1999

Applicant  
SMITHKLINE BEECHAM BIOLOGICALS S.A. et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized officer

Büchler, S

Tel. +49 89 2399-8090



# INTERNATIONAL COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>FB/BM45351</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/EP00/00137</b>	International filing date (day/month/year) <b>10/01/2000</b>	Priority date (day/month/year) <b>15/01/1999</b>
International Patent Classification (IPC) or national classification and IPC <b>C12N15/31</b>		
Applicant <b>SMITHKLINE BEECHAM BIOLOGICALS S.A. et al</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  <b>01/08/2000</b>	Date of completion of this report  <b>25.04.2001</b>
Name and mailing address of the international preliminary examining authority:   <b>European Patent Office</b> <b>D-80298 Munich</b> <b>Tel. +49 89 2399 - 0 Tx: 523656 epmu d</b> <b>Fax: +49 89 2399 - 4465</b>	Authorized officer  <b>Keller, Y</b>  Telephone No. <b>+49 89 2399 7419</b>





# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/00137

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, pages:**

1-58 as originally filed

**Claims, No.:**

1-24 as originally filed

**Drawings, sheets:**

1/15-15/15 as originally filed

**Sequence listing part of the description, pages:**

8, filed with the demand

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/00137

- ☐ the description,      pages:
- ☐ the claims,      Nos.:
- ☐ the drawings,      sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims	1-24
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-24
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	

2. Citations and explanations  
see separate sheet

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:  
see separate sheet

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
see separate sheet

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: WO 9802547

D1 discloses genes of *Neisseria meningitis* and the corresponding polypeptides (SEQ IDs). These genes and polypeptides can be used in the production of specific antibodies. Furthermore, the disclosed compounds can be used in methods (e.g. vaccines) of prevention of meningitis infection or detection of *Neisseria meningitis* (abstract; page 1, line 5 to 10, example 5 and 6).

1. D1 is considered as being the closest prior art among the documents cited in the international search report.
2. The main differences between D1 and the present Application are the DNA sequences and corresponding polypeptides used in the prevention of meningitis infection or detection of *Neisseria meningitis*.
3. The technical problem to be solved could be regarded as to clone other DNA sequences and the corresponding polypeptides used in the prevention of meningitis infection or detection of *Neisseria meningitis*.
4. D1 discloses that meningitis infection must be due to DNA sequences present in *N. meningitis* but absent in *N. gonorrhoea* and discloses such sequences as well. Being aware of this teaching the skilled person would have tried to isolate other DNA sequences and the corresponding polypeptides of *Neisseria meningitis*, and would have also had reasonable chances of success using standard techniques to obtain said DNA sequences and the corresponding polypeptides. The claimed sequences represent merely a selection of particular sequence among equally suitable sequences. Such a selection can only be regarded as inventive if a surprising or unexpected effect for the skilled person is shown. This

is not the case in the present Application.

Furthermore the use of non inventive sequence in common methods and/or products for which they have been obviously made for does not involve an inventive step.

Thus, claims 1-24 do not meet the requirements of Art 33 (3) PCT.

**Re Item VII**

**Certain defects in the international application**

6. No information as to the function of the claimed N. meningitis sequences is given in the application. The utilisation of said sequences for therapeutical purposes (vaccines, method of diagnostics) is purely speculative and relies on the sole origine of the claimed sequences.

Furthermore, the claimed polypeptides are defined as being immunogenic, such a characteristic can not be regarded as being a technical feature, any peptide, polypeptide can be considered as immunogenic since it triggers an immune response in animals.

The technical features of these polypeptides other than the sequences per se are not sufficiently disclosed in the present application. The examples do give hints to the skilled person for the determination of the hypothetic function wished by the Applicant but in no way does it permit to the skilled person to reproduce the present "invention" i.e the function of the claimed sequences, and their use as vaccines.

The invention is thus considered as insufficiently disclosed (Art. 5 PCT).

**Re Item VIII**

**Certain observations on the international application**

7. Claim 5 refers to an immunogenic fragment. Nevertheless, the description does not describe any particular immunogenic fragment of any polypeptide. Therefore, the subject matter of claim 5 is not based on the description. As no mention of a particular immunogenic fragment is made in the description the man skilled in the art would have to do an undue burden of experimentation to obtain an immunogenic fragment having characteristics equal to those listed in claim 5.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/EP00/00137

Thus the present application does not meet the requirements of Art. 5 and 6 PCT.

8. Claim 24 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).